UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In Re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL NO. 1456**
	Master File No. 01-CV-12257-PBS
	Judge Patti B. Saris
THIS DOCUMENT RELATES TO ALL ACTIONS	**Chief Mag. Judge Marianne B. Bowler**

THE TRACK 1 DEFENDANTS' MOTION FOR PROTECTIVE ORDER

The Track 1 Defendants hereby move for a protective order precluding Plaintiffs from taking the 30(b)(6) depositions noticed on May 27, 2004. As discussed below, the Track 1 Defendants' motion should be granted because the proposed areas of inquiry set out in Plaintiffs' May 27, 2004, 30(b)(6) notices relate to a new Medicare reimbursement system, based on a newly defined calculation known as "average sales price," that has not yet gone into effect and is wholly irrelevant to this action.[1] The "average sales price" system does not take effect until 2005, and the reporting obligations of Defendants under this system are still being developed by the relevant federal agency. Accordingly, the discovery Plaintiffs seek is wholly irrelevant to this action, and depositions on a reimbursement system that is not yet fully defined would be an unwarranted burden on Defendants.

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[1] The "Track 1 Defendants" are those Defendants identified as "Phase I fast track" Defendants in Case Management Order No. 10, entered by Judge Saris on March 25, 2004. Specifically, the Track 1 Defendants are AstraZeneca, the BMS Group (Bristol-Myers, OTN and Apothecon), the GSK Group (GlaxoSmithKline, SmithKline Beecham and Glaxo Wellcome), the Johnson and Johnson Group (J&J, Centocor and Ortho), and the Schering-Plough Group (Schering and Warrick).

BACKGROUND

A. Medicare Part B Reimbursement

Historically, the Medicare program did not generally cover the cost of prescription drugs. A limited number of physician-administered drugs, however, have been covered under Medicare Part B.[2] Through the Medicare Part B program, the federal government reimburses health care providers for up to 80 percent of the allowable cost of certain prescription drugs that they administer directly to patients. The remaining 20 percent is paid by the Medicare beneficiary in the form of a co-payment. Since 1992, Medicare has reimbursed healthcare providers for covered drugs using a formula set forth in federal regulations that is based on average wholesale price ("AWP"). 42 C.F.R. § 405.517 (1992). In 1997, Congress adopted the current AWP reimbursement standard by statute and mandated that payment for Covered Drugs be "based on the lower of the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological." 42 U.S.C. § 1395u(o). This standard was subsequently incorporated into the accompanying federal regulation, 42 C.F.R. § 405.517 (1992).

Congress and the Department of Health and Human Services did not define the term "average wholesale price" in the Medicare Part B statute or the accompanying regulations. Likewise, no statutory or regulatory directives exist to guide pharmaceutical manufacturers in calculating or reporting AWP. *See In re Pharmaceutical Indus. AWP Litig.*, 263 F. Supp. 2d 172, 178 (D. Mass. 2003). Pharmaceutical companies do not report AWPs directly to the federal government, but instead send pricing information to third-party publishing services that compile

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[2] The recently enacted Medicare Prescription Drug, Improvement, and Modernization Act of 2003, discussed below, expands prescription drug coverage.

the data and publish AWPs in trade publications. *Id.* The AWPs published by the third-party publishers are then used by the government in determining the amount of reimbursement for the health care provider.

B. The AWP MDL

In September 2002, Plaintiffs filed a Master Consolidated Class Action Complaint ("MCC") in this action, alleging that Defendants fraudulently inflated the AWPs of their Medicare Part B covered drugs by reporting pricing information to the third-party publishers that was higher than the prices actually paid by providers for those drugs, allegedly resulting in inflated co-payments for such drugs by Medicare beneficiaries. *See* MCC ¶ 3. Plaintiffs further alleged that they contracted with drug plan managers, known as Pharmacy Benefit Managers ("PBMs"). Because these contracts purportedly based the price of prescription drugs on the published AWPs, Plaintiffs alleged that they paid more for prescription drugs than they should have. The MCC asserted claims under RICO as well as under state consumer protection statutes. On May 13, 2003, Judge Saris granted in part a motion to dismiss the MCC. *See In re Pharm. Indust. AWP Litig.*, 263 F. Supp. 2d at 178-80.

On June 12, 2003, Plaintiffs filed the Amended Master Consolidated Class Action Complaint ("AMCC"), again alleging that Defendants fraudulently overstated the published AWPs of their prescription drugs, allegedly resulting in inflated payments by Medicare beneficiaries and other private payors. Like the MCC, the AMCC asserts claims under RICO and various state consumer protection statutes. The AMCC also adds a claim that certain Defendants engaged in an antitrust conspiracy through the Together Rx drug discount program. In her ruling granting in part Defendants' motion to dismiss the AMCC, Judge Saris outlined Plaintiffs' claims as follows:

> Plaintiffs allege three primary paradigms that accomplish this [AWP] fraud. First, Plaintiffs allege that each Defendant artificially raises its published AWPs to benefit medical providers (like doctors). The "spread" between the actual cost of the drug and the AWP encourages providers to use that Defendant's drugs at the expense of the beneficiaries of Medicare Part B who make co-payments. Second, Plaintiffs allege that each Defendant increases AWPs and provides other fraudulent kickbacks, discounts, and rebates to encourage pharmacy benefit managers to put its drugs on their formularies. Third, Plaintiffs allege that certain Defendant manufacturers participate in an antitrust and RICO conspiracy through a discount drug program, the Together Rx Program.

In re Pharm. Indust. AWP Litig., 307 F. Supp. 2d 196, 202-203 (D. Mass. 2004).

C. Defendants' Extensive Discovery Efforts

Following her February 24, 2004, ruling on the motions to dismiss the AMCC, Judge Saris issued Case Management Order No. 10, which set forth guidelines for management of this massive case of almost 20 defendants and 321 drugs. Judge Saris allowed Plaintiffs to conduct discovery with respect to all parties, claims and issues not dismissed under the February 24 order. Discovery and motions practice were broken down into two tracks. Track 1 consists of a fast track in which five Defendants (*see* n.1, *supra*), will litigate all phases of the case through summary judgment on an accelerated schedule. Under the Track 1 schedule, briefing on Plaintiffs' motion for class certification must be completed by December 8, 2004, and fact discovery must be completed by January 30, 2005. Briefing on summary judgment motions must be completed by May 30, 2005. Track 2 consists of a more extended schedule for the remaining Defendants.

The Track 1 framework alone involves over 100 different drugs -- nearly a third of the total identified in the AMCC. Since Judge Saris first permitted discovery to go forward in this case, the Track 1 Defendants have been responding to sweeping and extremely burdensome discovery requests on these drugs. Plaintiffs have noticed 30(b)(6) depositions covering twenty

different topics other than those that are the subject of this motion. *See* Amended Notice of Rule 30(b)(6) Deposition, dated April 2, 2004 (attached as Ex. 1). Plaintiffs have also issued three broad document requests.[3] In response to these requests, the Track 1 Defendants have so far produced well over three million pages of documents and tens of millions of records of transactional sales data at great cost. These productions are still ongoing, and many tens of thousands of additional pages will be produced.

D. The Present Discovery Dispute

In December 2003 -- over a year after the MCC was filed and six months after the AMCC was filed -- Congress passed the landmark Medicare Prescription Drug, Improvement, and Modernization Act ("2003 Medicare Act"), which, *inter alia,* replaces AWP with another, entirely new, pricing benchmark for certain drugs covered by Medicare Part B: Average Sales Price ("ASP"). The Act broadly defines ASP as an average of the final sales prices to all U.S. purchasers, net of rebates and other discounts. *See* 2003 Medicare Act 303(c). The new ASP is to be determined on a quarterly basis, based on data submitted by drug manufacturers.[4]

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[3] *See* Plaintiffs' Request for Production of Documents to Aventis, Abbott, Amgen, Boehringer, BMS, Johnson & Johnson, GSK, Hoffman, Immunex and Schering-Plough and Interrogatories to All Defendants Subject to Discovery, dated December 3, 2003 (attached as Ex. 2); Plaintiffs' Second Request for Production of Documents to Aventis, Abbott, Amgen, BMS, Johnson & Johnson, GSK, Hoffman, Immunex and Schering-Plough, dated December 19, 2003 (attached as Ex. 3); Plaintiffs' Omnibus Requests For Production And Interrogatories To Defendants Abbott, Amgen, Aventis, Baxter, Bayer, Boehringer, Braun, Dey, Fujisawa, Novartis, Pfizer, Pharmacia, Sicor, TAP And Watson And To All Other Defendants With Respect To Drugs That Were Not Previously Subject To Discovery, dated March 31, 2004 (attached as Ex. 4).

[4] The new ASP adds yet another pricing benchmark to those that are already in use for prescription pharmaceuticals. Besides AWP, there are several other benchmarks that have historically been used in the industry and by payors for determining payments and reimbursements for prescription drugs. One such pricing point is Average Manufacturer's Price ("AMP"), which unlike AWP is statutorily defined and used by the government to calculate rebates under the Medicaid rebate statute. *See* 42 U.S.C. § 1396r-8(c)(1)(B)(i). Another pricing (continued…)

Significant for purposes here, ASP will not be used to help set reimbursement levels until 2005. The Act maintained Medicare reimbursement at 95% of AWP for the balance of 2003. 2003 Medicare Act § 303(b). In 2004, reimbursements will generally equal 85% of AWP, although the Secretary of Health and Human Services is authorized to substitute a different percentage not lower than 80%. *Id.* Although reimbursement levels will not be based on ASP until 2005, the Medicare Act requires manufacturers to begin submitting ASP calculations in 2004 in order to accumulate the data necessary for this landmark change in reimbursement methodology.

CMS has not yet issued a final rule on ASP calculations. However, in order to give guidance for the reports that must be submitted in 2004, CMS issued an "interim final rule" on April 6, 2004. *See* Manufacturer Submission of Manufacturer's Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals, 69 Fed. Reg. 17935 (April 6, 2004). The first reports were due on April 30, 2004. On April 20, 2004, CMS held an open forum to provide guidance and answer questions on the ASP rule and subsequently published "Questions and Answers." *See Average Sales Price (ASP) Reporting, Questions and Answers*, available at http://www.cms.hhs.gov/providers/drugs/aspqa_web_042204.pdf. The concept of ASP is not self-defining, but rests on many assumptions and involves numerous technical issues. For example, in August 2003 -- before Congress enacted the 2003 Medicare Act -- CMS proposed a

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point is Wholesale Acquisition Cost ("WAC"), which constitutes a list price charged by drug manufacturers to wholesalers that is reported by some drug manufacturers to pricing publications. WAC is used by some state Medicaid programs and other payors as a benchmark to set reimbursement rates. *See* GAO, *Payments for Covered Outpatient Drugs Exceed Providers' Costs*, GAO-01-1118 (Sept. 2001), at 21 (available at http://www.gao.gov/new.items/d011118.pdf). Still other reimbursement levels are set by the Federal Supply Service, which purchases drugs for use by the Veterans Hospitals and other federal healthcare programs. *Id.*

methodology for calculating ASP that was materially different from the one contained in its interim rule. *See* 68 Fed. Reg. 50428 (Aug. 20, 2003).

Not surprisingly there has been considerable confusion over this new system. The comments submitted by the Pharmaceutical Research & Manufacturers of America ("PhRMA") demonstrate the many questions and issues left unresolved by the "interim final rule." *See* Ex. 5. In addition, two leading oncology groups -- the Association of Community Cancer Centers and the American Society of Clinical Oncology -- recently submitted comments to CMS expressing their concerns that the proposed methodology for calculating ASP could lead to artificially low ASPs and scenarios in which reimbursement rates to physicians are lower than the prices at which the physicians will be able to purchase the drugs. *See* "Cancer Groups Ask for Clearer Guidance on Part B Drug Reporting Requirements," 9 Health Care Daily Report (BNA) 113 (June 14, 2004) (attached as Ex. 6). CMS is currently considering these and other comments on the "interim final rule", and has indicated that it may amend its proposed methodology. *See* 69 Fed. Reg. 17936 ("As we gain more experience with the ASP system, we may seek to modify these [ASP reporting] requirements in the future.").

On May 27, 2004, Plaintiffs issued 30(b)(6) deposition notices to each of the Track 1 Defendants, identifying the following three areas of inquiry: (1) the identity of drugs with respect to which ASPs were submitted to the federal government pursuant to the Interim Medicare Regulations; (2) the identity of ASPs for each such drug; and (3) the AWP for each such drug. *See, e.g.*, Notice of Rule 30(b)(6) Deposition to GSK, dated May 27, 2004 (attached as Ex. 7). On behalf of the Track 1 Defendants, counsel for GSK informed Plaintiffs' counsel that the first two of these areas of inquiry (relating to ASPs) concerned post-complaint developments in the Medicare reimbursement methodology that have not yet gone into effect and

that were irrelevant to Plaintiffs' claims. Counsel for Plaintiffs have declined to withdraw the deposition notices, thus necessitating this motion. The parties agreed on a briefing schedule that called for Defendants' motion for protective order to be filed by June 15 and Plaintiffs' opposition by June 22, 2004.[5]

ARGUMENT

It is well established that matters irrelevant to the claims contained in the complaint are not subject to discovery. *See* Fed. R. Civ. P. 26(b)(1) ("Parties may obtain discovery regarding any matter . . . that is relevant to the claim or defense of any party."); *Public Serv. Co. of New Hampshire v. Hudson Light & Power Dep't*, 938 F.2d 338, 346-47 (1st Cir. 1991) (district court properly refused to allow discovery into irrelevant matters); *Assoc. for Reduction of Violence v. Hall,* 734 F.2d 63, 67 (1st Cir. 1984) (district court has discretion under Rule 26(b)(1) to prevent discovery on grounds of irrelevance). In addition, the broad scope of discovery authorized by Rule 26(b)(1) is subject to the limitations set out in Rule 26(b)(2), which permits a court to limit discovery if it determines, *inter alia,* that "the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case . . . and the importance of the proposed discovery in resolving the issues." *See also Ameristar Jet Charter, Inc. v. Signal Composites*, 244 F.3d 189, 193 (1st Cir. 2001) (district court has discretion to limit discovery where it would be an "undue burden").

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[5] On May 26, 2004, Plaintiffs issued a request for all documents (1) showing ASP or ASP information defendants have provided pursuant to the Interim Medicare Regulations for any of the drugs at issue; (2) concerning the Interim Medicare Regulations; and (3) exchanged with CMS concerning the Interim Medicare Regulations. *See* Plaintiffs' Request for Production to Defendants Regarding HHS ASPs, dated May 26, 2004 (attached as Ex. 8). Defendants intend to object to these requests on relevance and other grounds.

In particular, courts have refused to allow discovery into events occurring after the filing of the complaint that are entirely irrelevant to the plaintiff's claims. *See, e.g.*, *Daly v. Sprague*, 675 F.2d 716, 723-24 (5th Cir. 1982) (affirming refusal to allow additional discovery of events occurring after the filing of the suit because events in question were not relevant to plaintiff's claims). Here, Plaintiffs are seeking discovery of matters that not only took place after the MCC and the AMCC were filed, but will take place in the future -- the new ASP reimbursement system that does not go into effect until 2005.

The MCC, filed in September 2002, and the AMCC, filed in June 2003, allege that Defendants fraudulently manipulated the AWP-based system of reimbursement. Plaintiffs do not allege that Defendants have engaged in any wrongdoing with respect to ASPs, nor could they. ASP is a new calculation -- never before defined by statute or regulation or reported to any drug pricing publication -- that will not be the basis for any drug reimbursement until 2005. The definition of ASP set forth in the Act and in the interim regulations has no bearing whatsoever on the AWP pricing information Defendants reported under the AWP-based reimbursement system.

Furthermore, as an entirely new pricing benchmark, ASP is still a work in progress. The interim rule issued by CMS pursuant to which the Track 1 Defendants have made ASP reports is not yet final. Consequently, there remains a tremendous amount of uncertainty in how ASP should be calculated, and numerous parties have submitted comments to CMS identifying significant defects in its proposed method for calculating ASP. For example, PhRMA has pointed out, among other anomalies, that CMS's proposed methodology could result in drug manufacturers reporting a negative ASP. *See* Ex. 5 at 7. Indeed, CMS has already indicated that it may alter its proposed methodology for calculating ASP.

The five fast track Defendants -- the movants here -- are engaged in a massive discovery effort under exceedingly tight deadlines set by CMO 10. They literally have their hands full satisfying discovery requests on matters that are raised in the AMCC. There is no justification for permitting Plaintiffs to launch a fishing expedition into Defendants' efforts to comply with prospective regulatory requirements or the implementation of a reimbursement system that will not take effect until next year.

Discovery into Defendants' first tentative efforts -- under an interim rule that is subject to change -- to comply with a completely new regulatory regime that does not go into effect until next year imposes a burden that outweighs any benefit. *See* Rule 26(b)(2); *Signal Composites*, 244 F.3d at 193. Indeed, the discovery Plaintiffs seek on the prospective ASP system is of no importance in determining whether Defendants have acted unlawfully with respect to the AWP system. *See id.* Allowing Plaintiffs to initiate burdensome discovery every time there is a new development in the pharmaceutical industry would transform this case into an unbounded and continuous inquest.

CONCLUSION

For the reasons set forth above, the Track 1 Defendants respectfully request that the Court enter a protective order precluding the 30(b)(6) depositions noticed on May 27, 2004.

CERTIFICATION PURSUANT TO LOCAL RULE 7.1

Undersigned counsel hereby certify that they conferred in good faith with counsel for Plaintiffs and were unable to resolve the issue.

Respectfully submitted,

ON BEHALF OF TRACK 1 DEFENDANTS IN THE ABOVE-CAPTIONED ACTION,

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DATE: June 15, 2004

Counsel for SmithKline Beecham Corp., d/b/a GlaxoSmithKline

Certificate of Service

I hereby certify that on June 15, 2004, I caused a true and correct copy of The Track 1 Defendants' Motion for Protective Order to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2.

/s/
Jason R. Litow